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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,270	04/25/2007	Reto Luginbuehl	00366.000211.	3143

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EXAMINER

MONTANO, MELISSA ANN

ART UNIT	PAPER NUMBER
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3738

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,270	Applicant(s) LUGINBUEHL ET AL.	
	Examiner MELISSA MONTANO	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/13/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the hollow bodies, inner channel/channels, wall thickness of the channels, tubes, and the space between the tubes must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 46 recites the limitation "the articulating surface" in line 10. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 46, lines 10-11 recites "aligned perpendicularly to the plane of the articulating surface to more than 50%" and claim 47 recites "aligned to more than 90%, preferably more than 95%". The examiner is not sure whether applicant means that the hollow bodies cover more than 50% (or more than 90%, preferably more than 95%) of the articulating surface and are aligned perpendicularly to the plane of the articulating surface. The examiner encourages applicant to provide further explanation regarding this issue.

6. Claim 52 recites the limitation "the channels" in line 1. There is insufficient antecedent basis for this limitation in the claim. For the purposes of further examination, the examiner understands "the channels" to be referring to -- **the inner channel** --, as recited in claim 46.

7. Claim 68 recites the limitation "the material" in line 1. There is insufficient antecedent basis for this limitation in the claim. For the purposes of further examination,

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the examiner understands "the material" to be referring to -- **the bone substitute material** --, as recited in claim 62.

8. Claims 76 and 83 recite the limitation "the components" in line 2 and line 3, respectively. There is insufficient antecedent basis for this limitation in the claim. The examiner suggests that applicant amend the claims to recite the specific components that applicant means to claim.

9. Claim 79 recites the limitation "the polymeric component" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. For the purposes of further examination, the examiner understands "the polymeric component" to be referring to one of the -- **hollow bodies** --, as recited in claim 46.

10. Claim 81 recites the limitation "said components" in line 1. There is insufficient antecedent basis for this limitation in the claim. For the purposes of further examination, the examiner understands the "said components" to be referring to the -- **at least one externally added component** --, as recited in claim 80.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 46-90 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1064958 A1 to Vyakarnam (Vyakarnam).

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Vyakarnam teaches three-dimensional interconnected open cell porous foams that can be used to repair or regenerate tissue in humans (page 4, paragraph 0024). The foam structure taught by Vyakarnam is cylindrical in shape and has a diameter of 10mm and a depth (height) of 10mm. The examiner asserts that the foam structure shown in fig. 8 includes a hollow body component with a number of hollow bodies/tubes, as well as a base component and at least one superficial layer. The examiner also asserts that the diameter and depth taught by Vyakarnam would satisfy the limitations of a base component having a diameter ranging between 4-20mm and a height between 1-30mm, as well as hollow bodies having a height between 100 μ m and 10mm, as claimed by applicant. Features of the foam structure include interconnecting pores ranging from about 10 to 200 μ m that provide pathways for cellular ingrowth and nutrient diffusion, as well as channels that run through the foam for improved cell invasion, vascularization and nutrient diffusion (page 4, paragraph 0025, lines 8-13). The channels are at least 200 microns in length and may extend through the thickness of the foam. The diameter of the channel is one to three times the size of the average pore diameter (page 4, paragraph 0026, lines 37-40), which is taught to be 10 to 200 μ m, and therefore meets the limitations of the inner channel diameter ranging from 500nm to 500 μ m, as claimed by applicant.

Vyakarnam also teaches a superficial zone having collagen fibrils oriented to resist shear forces generated during normal joint articulation (page 5, paragraph 0029, lines 2-4). Fig. 8 shows that the superficial zone makes up 10-20% of the device at the uppermost end and therefore, through simple calculation (10% multiplied by 1-30mm),

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has a height of approximately 0.1mm-3mm, which meets the limitation of the superficial layer having a thickness of 1nm-5mm and/or 10µm-2mm, as claimed by applicant. The examiner asserts that fig. 8 also shows that the hollow bodies/tubes are aligned perpendicularly to the plane of the articulating surface to more than 50%, and more specifically to more than 90-95%, as claimed by applicant.

Further, Vyakarnam teaches that pores (spaces between tubes) of the foam may be partially or completely filled with biocompatible resorbable synthetic polymers or biopolymers or biocompatible ceramic materials and combinations thereof that may or may not include materials that promote tissue growth, such as autograft, allograft, or xenograft bone. Additionally, proteins, growth agents, therapeutic agents, or ceramic particles can be added to the foams (page 12, paragraph 0069). The examiner asserts that these additional components added to the foams would necessarily constitute at least one externally added component, including at least one of autologous cells, allogeneous cells, xenogeneous cells, transfected cells, and genetically engineered cells, as claimed by applicant. Channels formed in the foams, taught by Vyakarnam, may traverse the thickness of the foam and generally, foams formed in containers or molds have a thickness in the range from about 0.25mm to about 100mm. The thickness of these foams would necessarily meet the limitation of the channels having a wall thickness ranging between 1-100nm and 250-500µm, as claimed by applicant (p. 11, paragraph 0065, lines 24-25 and paragraph 0066, lines 38-39).

Further still, Vyakarnam teaches the creation of a foam with a gradient structure having variable pore size and structure as well as channels by applying a vacuum to a

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solid polymer-solvent mixture after it solidifies (page 10, paragraph 0061, lines 49-51).

The examiner asserts that the teaching of a foam made of a solid polymer-solvent mixture would necessarily include the fibers of the superficial layer and the material of the base component comprising synthetic polymers, as claimed by applicant. Foams with various structures are shown in fig. 2-4, for example the orientation of the major axis of the pores may be changed from being in the same plane as the foam to being oriented perpendicular to the plane of the foam (page 11, paragraph 0063). The examiner asserts that the variation in orientation of the structure of the foams would necessarily constitute hollow bodies of the component having a lateral distribution that is homogenous, random, or in a specific pattern, as claimed by applicant. The bottom of the structure, taught by Vyakarnam, is reinforced with ceramic particles or fibers made up of calcium phosphate and the like (page 5, paragraph 0030, lines 26-28). The examiner asserts that the bottom of the structure would necessarily constitute a base component comprising a bone substitute material that is a synthetic ceramic, specifically calcium phosphate, as claimed by applicant. The examiner further asserts that the calcium phosphate and ceramic particles, taught by Vyakarnam, would necessarily be selected from the group listed by applicant in claims 66 and 67, respectively.

Vyakarnam also teaches a compositionally gradient foam blend of two or more elastomeric copolymers or in combination with high modulus semi-crystalline polymers along with additives such as growth factors or particulates (page 5, paragraph 0032), which would necessarily meet the limitation of the base component material comprising at least two different components, as claimed by applicant. Fluid permeability is

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controlled by surface porosity, as taught by Vyakarnam, and the foams of Vyakarnam include porous layers having a porosity of about 80-95% or 50-80% (page 5, paragraph 0030, lines 14-24), which meets the limitation of the device having a liquid absorbing capacity in a range of 0.1-99.9% and 20-95%, as claimed by applicant. The examiner asserts that the fluid/liquid absorbed would necessarily be of an aqueous media and/or a body fluid, such as blood, as claimed by applicant. Vyakarnam further teaches suitable cells that may be contacted or seeded into the foam scaffolds include stem cells, osteoblasts, chondrocytes (page 13, paragraph 0075, lines 1-5). Further still, Vyakarnam teaches the creation tubular structures with gradients, such as in vascular grafts, that may or not include a barrier layer (cell barrier layer), with low porosity between two porous layers to increase strength and decrease leakage (page 7, paragraph 0040-0041). The examiner asserts that the barrier layer taught by Vyakarnam is necessarily capable of being a cell selective barrier layer, as claimed by applicant.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The reference US Patent No. 5,141,510 to Takagi et al. discloses a structure of artificial bone for use in implanting or grafting bone comprising tubular holes in a predetermined direction to ensure growth of new bone tissue after being implanted (fig. 2).

The reference US Patent No. 6,783,776 B2 to Spievack discloses a tissue regenerative composition comprising an epithelial basement membrane and connective tissue that appears to be in the form of hollow bodies (fig. 1A).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA MONTANO whose telephone number is (571)270-5785. The examiner can normally be reached on Monday-Friday 8:00AM-5:00PM EDT.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MM

/Bruce E Snow/
Primary Examiner, Art Unit 3738